K090940 #1/2

MAY 20 2009

Montreal, May 15, 2009.

510 (k) SUMMARY OF SAFETY AND EFFECTIVENESS

Applicant : Pega Medical Inc.
Autoroute Chomedey
Laval, Quebec H7W 5J8
Canada

Contact Person: Ariel R. Dujovne

Proprietary Name: Hinge Pediatric Plating System

Common Name: Pediatric Plate

Device Classification: Class II

Classification Name: Single/multiple component metallic bone fixation appliances and accessories 21 CFR 888-3030

Device Product Code: HRS/ HWC

Establishment Registration Number: 9048931

Intended Use: The Hinge Pediatric Plating System is indicated as a temporary implant to aid in the correction of the angle of growth of long bones by inhibiting longitudinal growth of the physis in pediatric patients. It can be used to correct the following conditions:

- Femur and tibia: varus, valgus, flexion or extension deformities of the knee.
- Humerus: valgus or varus deformities of the elbow.
- Radius and Ulna: flexion or extension deformities of the wrist.
- Ankle: varus, valgus or plantar flexion deformities of the ankle.

Description: The Hinge Pediatric Plating System is a three-component device made of Medical Grade Stainless Steel. The components are a plate and two screws of different sizes.

Basis for substantial equivalent:

The Hinge Pediatric Plating System is claimed to be substantially equivalent in design and function to the following predicate devices:

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1. Guided Growth Plate (Ti alloy plate and screws) University of Utah School of Medicine marketed as Eight Plate, Orthofix Inc. (K031493)
2. Pediplates System (Stainless Steel plate and screws), Orthopediatrics Inc. (K081407)
3. Growth Control Plating System marketed as Peanut Plate (Ti alloy plate and screws), Biomet Inc. (K070823)

The intended uses of these devices are the same as the Hinge Pediatric Plating System

Summary of Technologies: The technological characteristics of the Hinge Pediatric Plating System are the same or similar to the ones of the predicate devices.

Biomechanical Testing: A combined tension and bending test based on the ASTM standard F 564 "Standard Specifications and Test Method for Metallic Bone Staples" was performed to demonstrate safety. This test allows mechanical comparison of staples and bone plates devices indicated for the correction of angular deformities. The results indicated that the Hinge Pediatric Plating System is functionally safe for its intended use.

Clinical Testing: No clinical testing was provided as a basis for substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 20 2009

Pega Medical Inc.
% Ms. Ariel Dujovne
1105 Autoroute Chomedey
Laval, Quebec
Canada H7W 5J8

Re: K090440
Trade/Device Name: HINGE PEDIATRIC PLATING SYSTEM
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: February 17, 2009
Received: March 03, 2009

Dear Ms. Dujovne:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket.surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

For Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K090440
Device Name: **HINGE PEDIATRIC PLATING SYSTEM**
Indications for Use:

The Hinge Pediatric Plating System is indicated as a temporary implant to aid in the correction of the angle of growth of long bones by inhibiting longitudinal growth of the physis in pediatric patients. It can be used to correct the following conditions:

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- Ankle: varus, valgus or plantar flexion deformities of the ankle.

Prescription Use ____x___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use __no_____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Janeta J., PhD
(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

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